EXHIBIT B

Urology Group of New Jersey
UGNJ
777 Bloomfield Avenue
Glen Ridge, NJ 07028
973-429-0462 (phone) • 973-748-1236 (fax)
www.montclairurology.com
www.ugnj.com

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MDL No. 2327
	2:12-md-02327
THIS DOCUMENT RELATES TO:	HON. JOSEPH R. GOODWIN
April Berry, et al. v. Ethicon, Inc.., et al	

RULE 26 EXPERT REPORT OF KONSTANTIN WALMSLEY, MD

My name is Konstantin Walmsley. I have been retained by the Bern Ripka Law Firm to give medical opinions related to April Berry. I am being compensated at the rate of $500 dollars/hour. My curriculum vitae is attached to this report as **Ex. A**. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical and scientific certainty. My reliance list is attached as **Ex. B**.

I am a licensed physician in the State of New Jersey and a board certified urologist. I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices.

I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh, including mid urethral slings, and am familiar with the properties of these devices and proper implantation technique for these devices. Further, I am familiar with non-mesh options for the

Urology Group of New Jersey
UGNJ
777 Bloomfield Avenue
Glen Ridge, NJ 07028
973-429-0462 (phone) • 973-748-1236 (fax)
www.montclairurology.com
www.ugnj.com

treatment of stress urinary incontinence including autologous tissue based slings, biological graft-based slings, and periurethral bulking procedures. I have attended training provided by Ethicon, Inc. including training on TVT devices. Additionally, I have explanted and performed other revision procedures on transobturator and retropubic mid-urethral slings including the TVT device.

Additionally, in light of my training, knowledge, experience and qualifications as set forth above and in the attached C.V., I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants.

The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, and incomplete emptying), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients complications based upon a review of her medical records, and knowledge of her prior medical history.

Medical records reviewed include:

- Dr. Michael Heit
- Flaget Memorial Hospital
- Norton Suburban Hospital
- Dunn and Associates Physical therapy
- Dr. James Dodge
- Family Medical Center
- Louisville East Primary Care
- Total Woman Ob/Gyn

Clinical History

- On April 15, 2004, Mrs. Berry presented to Total Woman Ob/Gyn with complaints of pelvic pain. She described having ovulation-

Urology Group of New Jersey
UGNJ
777 Bloomfield Avenue
Glen Ridge, NJ 07028
973-429-0462 (phone) • 973-748-1236 (fax)
www.montclairurology.com
www.ugnj.com

dependent cramping and pain. She also complained of dyspareunia that her doctor attributed to the position of her uterus. No treatment was recommended at this time.

- On April 25, 2006, Mrs. Berry presented to Dr. James Dodge as a 34 year old female G3P3 with a history of abnormal menstrual bleeding. Past medical history was remarkable for GERD, incontinence, seasonal allergies and scoliosis. There was also a history of sexual abuse as a child. Physical examination revealed a grade 2 cystocele and urethral hypermobility. Of note, she was sexually active with no complaints of dyspareunia at this time.

- On July 14, 2006, Mrs. Berry underwent hysteroscopy, dilation and curettage, Thermachoice endometrial ablation, tension-free vaginal tape (transobdurator approach), anterior colporraphy using Prolift mesh, and cystoscopy by Dr. James Dodge. The TVT-O sling was placed in a tension-free fashion.

- On July 17, 2006, Mrs. Berry saw Dr. Dodge with complaints of pain and headache. She was diagnosed with candidal vulvovaginitis and prescribed Diflucan.

- On August 21, 2006, Mrs. Berry saw Dr. Dodge with complaints of abdominal soreness. Physical exam revealed moderate banding of the superior Prolift bands with tenderness at the margins laterally, consistent with Dr. Dodge's assessment of "tightened banding".

- On August 29, 2006, Mrs. Berry saw Dr. Dodge with complaints of pelvic pain and dyspareunia. Physical exam of her vaginal vault revealed banding present on the superior anterior segment of the Prolift bilaterally. She was scheduled for mesh release and revision.

- On September 1, 2006, Mrs. Berry underwent partial excision and revision of Prolift mesh at the inferior and superior borders by Dr.

Urology Group of New Jersey
UGNJ
777 Bloomfield Avenue
Glen Ridge, NJ 07028
973-429-0462 (phone) • 973-748-1236 (fax)
www.montclairurology.com
www.ugnj.com

Dodge. Exam under anesthesia revealed a small banjo string section of exposed mesh in the right anterior superior angle of the vagina just posterior to the pubic ramus. There was old retention in the left lower angle of the vagina as well and in the anterior fornix there was noted to be overtightening and a small area of mesh exposure on the right. The exposed mesh was resected and careful mesh release was performed of each of these areas.

- On September 13, 2006, Mrs. Berry saw Dr. Dodge with left-sided vaginal pain. Pelvic exam revealed marked tenderness to palpation at the left anterior tape and bilaterally at the apex near the cervix. "Very tense mesh" was noted.

- On September 21, 2006, Mrs. Berry saw Dr. Heit because of dyspareunia, with the patient describing feeling like she had barbed wire sticking in her vagina, and complaining of a "tight vagina after prior mesh procedure". Despite having "the right side taken out", she was still having similar problems. Mrs. Berry stated that she still felt like there was tension and pulling in the vagina. Physical exam revealed erosion of synthetic mesh coming down from the right middle anterior vagina distally as well as proximally. There was also evidence of the mesh placed distally instead of over the full length of the vaginal wall. Removal of the anterior vaginal wall mesh was recommended.

- On September 26, 2006, given the diagnosis of dyspareunia secondary to anterior vaginal wall mesh, and Prolift mesh exposure at multiple sites, Mrs. Berry underwent excision and removal of Prolift mesh by Dr. Michael Heit. The entire right and left vagina were dissected away from the underlying mesh to the pelvic sidewalls. The mesh was incised in its midline, grasped at its edges with Kocher clamps, and dissection was then undertaken to the right and left pelvic sidewalls to the lateral aspect of the mesh. The mesh itself had been rolled on itself at the bladder neck and was not lying flat to the apex at the vagina. The vagina was then closed with 2-0 Vicryl sutures.

Urology Group of New Jersey
UGNJ
777 Bloomfield Avenue
Glen Ridge, NJ 07028
973-429-0462 (phone) • 973-748-1236 (fax)
www.montclairurology.com
www.ugnj.com

- On September 29, 2006, Mrs. Berry saw Dr. Heit for a post-op visit. Her dyspareunia was no better and she complained of feeling a "fishing line" in her vagina distally. Dr. Heit memorialized that "in retrospect, her dyspareunia was introital rather than deep because [her husband] could never get pas[t] the distal vagina to test the impact of Prolift mesh." Physical exam revealed that the TVT-O tape had twisted on the left side right behind the pubic bone. Because of dyspareunia and pain radiating down the left leg, the patient requested removal of the TVT-O mesh.

- On November 10, 2006, because of significant dyspareunia not resolved by anterior Prolift removal, Dr. Heit performed removal of Mrs. Berry's TVT-O mesh. He identified erosion of the left arm of the mid-urethral sling mesh and removed the entire intra-vaginal portion of the mesh from one pelvic sidewall to the other pelvic sidewall.

- On December 5, 2006, Mrs. Berry saw Dr. Heit. She had intercourse once since her last surgery describing "swelling" with remarkably less pain. There was some pulling from mesh arms while "up" with radiation to the left leg. Physical exam revealed no palpable mesh periurethrally.

- On March 29, 2007, Mrs. Berry saw Dr. Heit with continued dyspareunia with a current pain scale of 5/10 (having gone from a 10/10 pre-op to a 2/10 after her first mesh excision). Her pain was more on the left side than the right. She also noted feeling a pulling sensation her groin (left>right) and with change in position. Despite discussions regarding complete TVT excision, Dr. Heit concluded that this was too aggressive an approach and recommended further mesh excision.

- On April 23, 2007, Mrs. Berry underwent synthetic removal of allograft by vaginal route by Dr. Michael Heit. During this procedure, Dr. Heit removed the distal TVT-O arms extending out

Urology Group of New Jersey
UGNJ
777 Bloomfield Avenue
Glen Ridge, NJ 07028
973-429-0462 (phone) • 973-748-1236 (fax)
www.montclairurology.com
www.ugnj.com

towards the ischiopubic rami, removing approximately 1 inch segments from each side of the pelvic sidewall. Pathologic analysis of the mesh specimens revealed squamous mucosa and benign fibrous tissue with foreign body giant cell reaction.

- On June 5, 2007, Mrs. Berry saw Dr. Heit with some fatigue and residual discomfort. She was having less problems with vaginal swelling and irritation when she is aroused than when she is not aroused during intercourse.

- Between January 2, 2008 and March 6, 2008, Mrs. Berry received physical therapy for abdominal/groin pain, pelvic pain, and urinary incontinence. At the culmination of her therapy, she had pain at a scale of 1/10 with mild to moderate activity; superficial pelvic floor soft tissue mobility with some mild palpation pain remaining at the perineal body; and deep intravaginal pain remaining with palpation scar tissue. She was continuing to have dyspareunia with deep palpation.

- On April 17, 2008, Mrs. Berry was seen By Dr. McCoy at Family Medical Center for a well woman exam. Pelvic exam revealed mild uterine prolapse and an area within the vaginal canal at 9 to 12 o'clock of the cervix with a hard ½ cm knot x 2 tender to palpation.

- On February 18th, 2009, Mrs. Berry was diagnosed with a UTI and treated with Cipro.

- On August 24th, 2009, Mrs. Berry was seen By Dr. McCoy at Family Medical Center for a well woman exam. Complaints included mild stress urinary incontinence (SUI). Pelvic exam revealed mild uterine prolapse and an area within the vaginal canal at 9 to 12 o'clock of the cervix with a hard ½ cm knot x 2 tender to palpation.

Urology Group of New Jersey
UGNJ
777 Bloomfield Avenue
Glen Ridge, NJ 07028
973-429-0462 (phone) • 973-748-1236 (fax)
www.montclairurology.com
www.ugnj.com

Methodology

My general opinions based upon my clinical experience and review of medical and scientific literature and well as my medical education, knowledge, training, practice, and clinical experience.

My case specific opinions are based upon a differential diagnosis methodology. In determining the specific cause of an injury in the medical context it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause.

General Opinion No. 1

Facilitating informed consent is an integral part of the practice of medicine. I agree with AMA 8.08 on informed consent. The patient's right of self-decision is particularly important when surgical intervention regarding a permanent medical device is being considered by the patient.

Before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure, including the TVT, the surgeon must be informed on the risks/benefits/alternatives. I have read and relied on Instructions for Use (IFU) for medical devices when informing myself on the risks/benefits/alternatives to a given procedures – including mid-urethral slings. I incorporate the risks and complications referenced in the IFU into my risk-benefit conversation with the patient. I expect the risk and complication information as presented in the IFU to be accurate.

It is my opinion the IFU for the TVT in 2006 was not sufficient to enable informed consent from the patient. The TVT IFU provided:

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.

Urology Group of New Jersey
UGNJ
777 Bloomfield Avenue
Glen Ridge, NJ 07028
973-429-0462 (phone) • 973-748-1236 (fax)
www.montclairurology.com
www.ugnj.com

- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction (i.e. too much tension) applied to the tape may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

The words "transitory" and "transient" carry a specific medical meaning. Mosby's medical dictionary defines transient as "pertaining to a condition that is temporary." Using the word transient to describe the human body's foreign body response to the TVT mesh implies the response dissipates with time. In my experience, this does not accurately describe the human body's foreign body response to transvaginal placed mesh.

In my experience when dealing with synthetic mesh-induced foreign body response, the degree of inflammation and scarring around the mesh is intense and chronic. More often than not, when removing exposed mesh, I am unable to completely remove the entire mesh implant because of the intensity of inflammation and extensive scarring induced by mesh incorporation into the host tissues. Moreover, in all of my experiences removing mesh, residual scarring of the vagina, peri-vaginal, and those tissues adjacent to the mesh persists and is even more severe in the instances where residual pelvic mesh is left in the patient.

The TVT IFU does not mention: mesh contraction; dyspareunia; mesh shrinkage; scar plate formation; or the difficulty in removing mesh in the event of an adverse event. These events are all part of my informed consent conversation

Urology Group of New Jersey
UGNJ
777 Bloomfield Avenue
Glen Ridge, NJ 07028
973-429-0462 (phone) * 973-748-1236 (fax)
www.montclairurology.com
www.ugnj.com

today. I have treated patients implanted with mid-urethral slings, including the TVT for these conditions. It is my opinion that a patient considering a mid-urethral sling cannot be properly consented without discussing these potential adverse events.

General Opinion No. 2

In 2006, alternative successful and safer sling procedures were available, including autologous fascial slings using rectus fascia sutured to the bladder neck and tied to itself over the rectus fascia. Mrs. Berry was unable to receive proper informed consent relating to this safer alternative because of the lack of information in the TVT IFU inherent to the risks of using synthetic mesh. As such, Dr. Dodge was unable to warn Mrs. Berry of the subsequent complications she has suffered from.

Case Specific Opinion No. 1

Mrs. Berry suffered mesh erosion and vaginal sling contraction as a result of the physical properties of the TVT device. These conditions are documented in the medical records.

A. Erosion

Mrs. Berry's vaginal sling exposure was caused by a mesh-specific acute and chronic inflammatory response with resultant retraction and shrinkage of the mesh. Recognized causes of sling exposure include: (1) a surgical error in implantation technique; (2) atrophy of the vaginal tissue surrounding the device; and (3) changes to the physical properties of the device post-implantation including, but not limited to, retraction, shrinkage, fraying, roping and curling.

A surgical technique error can be reasonably excluded as a cause of the exposure. Dr. Dodge placed the TVT-O sling in a manner consistent with the technique outlined in the IFU, with the mesh being adjusted to tension-free status when placed.

There is no evidence of vaginal atrophy nor is Mrs. Berry in a post-menopausal state so this may be ruled out as a cause of her erosion.

Based on the foregoing analysis, it is my opinion to a reasonable degree of medical probability that the cause of Mrs. Berry's sling exposure

Urology Group of New Jersey
UGNJ
777 Bloomfield Avenue
Glen Ridge, NJ 07028
973-429-0462 (phone) • 973-748-1236 (fax)
www.montclairurology.com
www.ugnj.com

was primarily caused by a mesh-specific acute and chronic inflammatory response causing changes in the physical properties of the sling, namely retraction and shrinkage. Of note, there is no evidence of fraying, roping, or curling of the TVT product. Around the time of explant, Mrs. Berry described a "fishing line" sensation in her distal vagina consistent with retraction and shrinkage. This is further supported by the pulling sensation described by Mrs. Berry which persisted beyond the first TVT mesh removal procedure and was a contributing factor leading to the second TVT removal procedure. Additionally, not only did Dr. Heit find that the sling twisted on the left side behind the pubic bone, but Mrs. Berry's complaints were also primarily left-sided with multiple complaints of a pulling sensation consistent with mesh retraction and shrinkage.

B. Contraction

Mrs. Berry's TVT contracted post implantation. This finding is supported by the evidence discussed above. Additionally, during Mrs. Berry's visit to Dr. Heit in December of 2006, she described "some pulling from the mesh arms consistent with mesh contraction. I have observed mesh contraction in my clinical practice. The post-implantation shrinkage of the mesh involves a combination of two factors: one being the mesh itself contracting and the other being the foreign body response generating a fibrotic response that entails wound contracture.

C. Failure to Incorporate

Portions of the TVT device failed to incorporate into Mrs. Berry's surrounding tissues. Her early erosion event, less than 4 months following insertion of the TVT device confirms this. Moreover, Dr. Dodge's surgical technique was appropriate and she had no evidence of vaginal atrophy at the time of her surgeries.

I have observed failure of mesh to incorporate in my clinical practice.

Urology Group of New Jersey
UGNJ
777 Bloomfield Avenue
Glen Ridge, NJ 07028
973-429-0462 (phone) • 973-748-1236 (fax)
www.montclairurology.com
www.ugnj.com

Case Specific Opinion No. 2

Mrs. Berry's erosion in 2006 was caused by the physical properties of the TVT – specifically, the retraction and shrinkage of the TVT. As stated above, recognized causes of sling exposure include: (1) a surgical error in implantation technique; (2) atrophy of the vaginal tissue surrounding the device; and (3) the physical properties of the device post-implantation including, but not limited to, retraction, shrinkage, contraction, fraying, roping and curling.

I am able to rule in the physical properties of the TVT, including the edge of the TVT, based on the discussion set forth in Case Specific Opinion No. 1.

I am able to rule out vaginal atrophy and surgical error as detailed in Case Specific Opinion No. 1.

Case Specific Opinion No. 3

Mrs. Berry's vaginal pain and dyspareunia was caused by her sling extrusion and contraction of the TVT device. Recognized causes of dyspareunia following synthetic sling surgery include: (1) erosion/extrusion; (2) mesh contraction; (3) paraurethral banding; (4) scarring with reduced elasticity; (5) infection and inflammation including but not limited to vestibulitis; (6) neuromuscular injury; (7) lichen sclerosis; (8) vaginal tissue atrophy; and (9) pelvic floor dysfunction.

I am able to rule in erosion, contraction and scarring as potential causes of Mrs. Berry's vaginal pain and dyspareunia. These conditions are documented in the medical records of Dr. Heit as previously discussed. Further, during Mrs. Berry's second TVT explant procedure in April of 2007, pathologic review of the mesh explant revealed foreign body reaction. This is part of the chronic inflammatory response that polypropylene mesh induces as part of the scarring process. Her complaints of "pulling", especially on the left side, underscore the diminished elasticity of the vaginal tissues, which occurs as part of the scarring process.

Urology Group of New Jersey
UGNJ
777 Bloomfield Avenue
Glen Ridge, NJ 07028
973-429-0462 (phone) • 973-748-1236 (fax)
www.montclairurology.com
www.ugnj.com

I am able to exclude paraurethral banding as a cause of Mrs. Berry's dyspareunia and vaginal pain because I have not seen paraurethral banding documented.

Additionally, I am able to exclude infection, inflammatory states, vaginal tissue atrophy, and neuromuscular injury as causes of Mrs. Berry's vaginal pain and dyspareunia as there is no evidence of these conditions in her medical records

I am able to exclude pelvic floor dysfunction as a significant cause of Mrs. Berry's vaginal pain and dyspareunia. Although she had some pelvic muscle palpation tenderness during her physical therapy treatments, the majority of her vaginal pain (and all of her dyspareunia) related to the palpable intravaginal scar tissue. Interestingly, the majority of her pelvic floor dysfunction was improved with physical therapy whereas the vaginal scar tissue-related vaginal pain and dyspareunia persisted.

Case Specific Opinion No. 4

Mrs. Berry's future prognosis as it relates to her pelvic pain, dyspareunia, and voiding dysfunction is guarded. Mrs. Berry continues to have pelvic pain and dyspareunia presently. During her well woman visits, she has continued to have tenderness documented by pelvic exams revealing an area within the vaginal canal at 9 to 12 o'clock of the cervix with a hard ½ cm knot x 2 tender to palpation. She has recurrent SUI. Additionally, she has pelvic tenderness and residual scar tissue in the area where her mesh erosions have been treated. The multiple surgeries she has already had performed by Drs. Dodge and Heit have resulted in residual fibrosis and scarring in the area of her mesh erosions.

In as much an autologous fascial sling for incontinence might be considered, the success rates of these procedures are lessened in a previously operated surgical field. In addition, complication rates are increased. In summary, within a reasonable degree of medical certainty, the voiding dysfunction, pelvic pain, and dyspareunia will be a lifelong condition for this patient.

Urology Group of New Jersey
UGNJ
777 Bloomfield Avenue
Glen Ridge, NJ 07028
973-429-0462 (phone) • 973-748-1236 (fax)
www.montclairurology.com
www.ugnj.com

These represent my current opinions in this case. As any additional material becomes available, I reserve the right to modify or add to this opinion.
Dated this the 22nd day of July, 2016

Sincerely,

Konstantin Walmsley, M.D.